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EXAMINER

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/805,813	Applicant(s) Ichiro Mitsuhashi, et al.
	Examiner Amy Nelson	Group Art Unit 1649

Responsive to communication(s) filed on Nov 16, 1998.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-20 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 1-20 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 10

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. Applicant's amendments filed 11/16/98 and 12/7/98 have been entered. The final rejection of 8/10/98 is hereby withdrawn.

Information Disclosure Statement

2. References AA, AB, AC in the Information Disclosure Statement filed 8/5/98 were considered, but will not be published because they were incorrectly listed as U.S. Patent Documents rather than Foreign Patent Documents. References AR and AT were considered but will not be published because they are incomplete citations and do not include publication dates. If Applicant would like the references to be published, they should be resubmitted in a Supplemental Information Disclosure Statement with the appropriate corrections.

Claim Objections

3. Claim 14 is objected to because of the following informalities:

At line 2, "Sarcotomin" is misspelled and should be changed to --Sarcotoxin--.

Claim Rejections - 35 USC § 112

4. Claims 1-3, 5-13, 15, 16, and 18-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is drawn broadly toward a gene encoding an anti-bacterial peptide. Applicant describes the composition and structure of a single gene encoding an anti-bacterial peptide, namely sarcotoxin 1a, and hence it is not clear from the instant specification that the Applicant was in possession of the invention as broadly claimed.

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

5. Claim 1-3, 5-13, 15, 16, and 18-20 remain rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling only for claims limited to a recombinant gene, expression vector, and transgenic plant comprising the sarcotoxin 1a gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official actions mailed 3/31/98 and 8/10/98. Applicant's arguments filed 11/16/98 have been fully considered but they are not persuasive.

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Applicant asserts that routine screens to identify other genes within the scope of the claims were well known at the time of the invention, and asserts that the Epple reference provides evidence that a transgenic plant with fungal resistance was in fact produced by the same method as the instant invention (response, p. 5). While it is true that methods for identification of other anti-bacterial genes are known in the art, undue trial and error experimentation would be required to screen through the vast number of cDNA and genomic clones from a dipteran insect or an other organism to identify those which encode proteins with activity against bacteria. Applicant has provided no guidance with respect to structural or functional characteristics, or with respect to hybridization/wash conditions or PCR reaction conditions which would allow isolation of other anti-bacterial genes, particularly those that would confer anti-fungal properties on plants transformed therewith. Moreover, there is no teaching in the instant application which would lead to the isolation and expression of the thionin gene as taught by Epple. Hence, the broad scope of the claims is not commensurate with the teachings of the specification and the invention is not enabled.

6. Claims 5-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is unclear because it is not known how a “gene” can be a “recombinant gene” or an “expression cassette” or an “expression vector.” It is recommended that “gene” at line 1 be

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changed to --DNA molecule-- and that Claim 1 be amended accordingly. Also, it is recommended that at line 2, “in a form” is changed to --is--.

Claim 12 is unclear because it is not known how a “gene” can be a “recombinant gene” or an “expression cassette” or an “expression vector.” It is recommended that “gene” at line 1 be changed to --DNA molecule--.

At Claim 16, line 3, “the Diptera insect” should be changed to --a Diptera insect-- because it refers to any Diptera insect.

At Claim 17, line 2, “the Diptera insect” should be changed to --a Diptera insect-- because it refers to any Diptera insect.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

8. Claims 1-5, 10 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Jaynes *et al.* (U.S. Patent 5,597,945).

Jaynes teaches transgenic plants transformed with a gene encoding an anti-bacterial peptide (abstract). Although Jaynes exemplifies the anti-bacterial peptides, cecropin, attacin and

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lysozyme, Jaynes also discloses many other suitable anti-bacterial genes, including sarcotoxin 1a (col. 7, lines 39 - col. 8, line 10). Jaynes teaches the expression of the anti-bacterial genes in expression vectors, and specifically discloses T-DNA vectors (col. 15-16). Furthermore, Jaynes teaches that the transgenic plants have resistance to fungal pathogens (col. 7, lines 32-38; Examples 11, 14 and 15, for example). It is expected that the disclosed transgenic plants would also exhibit resistance to other fungal pathogens, including *Rhizoctonia solani*, *Phythium aphanidermatum*, and *Phytophtora infestans*, as Jaynes teaches genes that have general anti-microbial properties. The antifungal properties are inherent properties of the disclosed transgenic plants of Jaynes. Hence, all of the claim limitations have been previously disclosed by Jaynes.

9. Claims 1, 2 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Broekaert *et al.* (U.S. Patent 5,538,525).

Broekaert teaches transgenic plants transformed with a gene encoding an anti-bacterial peptide (abstract). The genes isolated by Broekaert are isolated from plants. Broekaert teaches the expression of the anti-bacterial genes in expression vectors, and specifically discloses T-DNA vectors (Examples 23-25). Furthermore, Broekaert teaches that the transgenic plants have resistance to fungal pathogens (Abstract, col. 4, for example). It is expected that the disclosed transgenic plants would also exhibit resistance to other fungal pathogens, including *Rhizoctonia solani*, *Phythium aphanidermatum*, and *Phytophtora infestans*, as Broekaert teaches genes that have general anti-microbial properties. The antifungal properties are inherent properties of the

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disclosed transgenic plants of Broekaert. Hence, all of the claim limitations have been previously disclosed by Broekaert.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jaynes *et al.* (U.S. Patent 5,597,945) in view of Applicant's admission.

The teachings of Jaynes are discussed *supra*.

Jaynes does not teach expression vectors and transgenic plants also comprising a plant gene, the hinge region of a tobacco chitinase gene, a signal sequence, or the tobacco PR-1 promoter, nor plants with resistance to *P. syringae* pv. *tabaci* or *E. carotovora* subsp. *carotovora*.

Applicant admits that the hinge region of tobacco chitinase was well known in the art as taught by Shinshi (Specification, p. 9, lines 25-33), and Applicant also teaches that the PR-1 promoter was known in the art (Specification, p. 9, lines 5-17).

It would have been obvious to modify the recombinant genes and expression vectors of Jaynes, and the plants transformed therewith, to include other well known regulatory elements,

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including promoters such as the tobacco PR-1 promoter, or a signal sequence for subcellular targeting, or other plant genes or portions thereof, including the hinge regions of tobacco chitinase, as such elements were well known in the art at the time of Applicant's invention. Such modification of the recombinant genes, expression vectors, and transgenic plants would be encompassed by the normal range of experimentation based on the teachings of Jaynes. Applicant has provided no evidence of unexpected results by inclusion of any of the claimed elements, and hence the inclusion of the other elements is deemed obvious in view of Jaynes.

12. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Broekaert *et al.* (U.S. Patent 5,538,525) in view of Applicant's admission.

The teachings of Broekaert are discussed *supra*.

Broekaert does not teach the antibacterial gene, sarcotoxin 1a, nor does Broekaert teach expression vectors and transgenic plants comprising, in addition to an anti-bacterial gene, a plant gene, the hinge region of a tobacco chitinase gene, a signal sequence, or the tobacco PR-1 promoter. Furthermore, Broekaert does not teach plants with resistance to *P. syringae* pv. *tabaci* or *E. carotovora* subsp. *carotovora*.

Applicant admits that the sarcotoxin 1a gene was known at the time of the invention (Specification, p. 2, lines 9-22). Applicant also admits that the hinge region of tobacco chitinase was well known in the art as taught by Shinshi (Specification, p. 9, lines 25-33), and Applicant teaches that the PR-1 promoter was known in the art (Specification, p. 9, lines 5-17).

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It would have been obvious to modify the invention of Broekaert to substitute the anti-microbial sarcotoxin 1a gene for the disclosed plant anti-microbial genes, because anti-microbial genes are functional equivalents and it would have been obvious to substitute one functional equivalent for another. It also would have been obvious to modify the recombinant genes and expression vectors of Broekaert, and the plants transformed therewith, to include other well known regulatory elements, including promoters such as the tobacco PR-1 promoter, or a signal sequence for subcellular targeting, or other plant genes or portions thereof, including the hinge regions of tobacco chitinase, as such elements were well known in the art at the time of Applicant's invention. Such modification of the recombinant genes, expression vectors, and transgenic plants would be encompassed by the normal range of experimentation based on the teachings of Broekaert. Applicant has provided no evidence of unexpected results by inclusion of any of the claimed elements, and hence the inclusion of the other elements is deemed obvious in view of Broekaert.

Response to Arguments

13. Applicant's arguments filed 11/16/98 have been fully considered but they are not persuasive.

Applicant asserts that neither of the prior art references confirm that transgenic plants with anti-fungal activity were actually obtained. Applicant also argues that Jaynes teaches resistance to bacteria, which are classified completely differently from fungi (response, p. 6). The

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instant claims are drawn to transgenic plants *per se*, and not to methods of conferring fungal resistance on plants. Hence, it is submitted that the claimed invention reads on the transgenic plants of Broekaert and Jaynes. Fungal resistance is an inherent property of the plants disclosed by either Broekaert or Jaynes. There is reasonable evidence to suggest that the disclosed plants have the phenotype of fungal resistance given the anti-microbial (both anti-bacterial and anti-fungal) properties of the introduced genes. Also both Broekaert and Jaynes specifically discuss the use of the anti-microbial genes to obtain plants with fungal resistance (see Broekaert, Abstract, col. 4; Jaynes, col. 7, lines 32-38; Examples 11, 14 and 15, for example). Hence, the burden is shifted to Applicant to provide evidence that the prior art plants do not have anti-fungal properties.

Furthermore, Applicant asserts that the instant invention is novel over the prior art in the teaching of the insertion of the tobacco chitinase hinge region into the vectors between the anti-bacterial gene and a plant gene, to allow better accumulation of the anti-bacterial peptide (response, p. 7). Applicant has provided no side-by-side comparisons between the vectors of the instant invention (comprising the hinge region) and the prior art vectors (equivalent vectors without the hinge region) to substantiate their assertions of nonobviousness. Absent of evidence of unexpected results with vectors comprising the hinge region, it is submitted that the vectors and transformed plants of the instant invention would have been obvious in view of either Jaynes or Broekaert.

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Claim Rejections - 35 USC § 101

14. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

15. Claims 1-4 and 20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims read on naturally occurring plants, which are products of nature and not one of the five classes of patentable subject matter. Amendment of the claims to insert --transgenic-- would obviate this rejection.

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16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy J. Nelson whose telephone number is (703) 306-3218. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Douglas Robinson, can be reached at (703) 308-2897. The fax phone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Amy J. Nelson, Ph.D.

December 11, 1998



Douglas W. Robinson
Supervisory Patent Examiner
Technology Center 1600